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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,486	03/30/2000	SERGEY A. SELIFONOV	02-028940US	8406

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BEYER WEAVER & THOMAS LLP
P.O. BOX 70250
OAKLAND, CA 94612-0250

EXAMINER

ZHOU, SHUBO

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/539,486

Applicant(s)

SELIFONOV ET AL.

Examiner

Shubo (Joe) Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/4/03, 3/15/04, 5/17/04, 9/14/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24,26-29,31-46,99 and 100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24,26-29,31-46,99 and 100 is/are rejected.
- 7) ☒ Claim(s) 2 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/13/02, 1/30/02, 3/17/03, 12/14/03, 3/15/04, 5/17/04, 10/4/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to RCE and Amendment

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions and amendments filed on 8/4/03, 10/14/03, 3/15/04, 5/17/04, 9/14/04, and 10/4/04 have been entered. Claims pending and under consideration are 1-24, 26-29, 31-46, 99-100.

2. The rejections of claims 1-4, 6-9, 12-29, 31-38, 40-46, and 99-100 under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. (IDS document: Nature Biotechnology, Vol. 16:258-261, March, 1998) in view of Ho et al. (US patent No. 5023171, date of patent: Jun. 11, 1991) are hereby withdrawn in view of the amendments to the claims filed 9/14/04.

3. The rejections of claims 1-29, 31-38, 40-46, 93-98, and 101 under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. (IDS document: Nature Biotechnology, Vol. 16:258-261, March, 1998) in view of Ho et al. (US patent No. 5023171, date of patent: Jun. 11, 1991) and Venkatasubramanian et al. (J. Chem. Inf. Comput. Sci. 1995, 33, 188-195), and in further view of Street et al. (IDS document: Structure, May 1999, 7:R105-R109) are hereby withdrawn in view of the amendments to the claims filed 9/14/04.

4. The objections to claims 30 and 39 as being dependent upon a rejected base claim is hereby withdrawn in view of the amendments to the claims filed 9/14/04.

Declaration

5. The declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The declaration filed 7/13/00 is defective because inventor Lorraine J. Giver signed but not dated the declaration.

Information Disclosure Statements

6. The Information Disclosure Statements filed on 1/17/02, 1/30/02, 3/17/03, 10/14/03, 3/15/04, 5/17/04, and 10/4/04, respectively, are entered and references therein have been considered except reference C23 of the IDS filed 3/17/03 because no publication date was provided for the reference. A signed copy of each PTO-1449 is herein attached.

Specification

7. The specification is objected to because of the following:

Trademarks are used in this application, such as GENBANKTM on page 36. Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification on 9 and other pages.

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Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code on this page and such codes anywhere else in the specification. See MPEP '608.01.

8. Appropriate correction is required.

Claim Rejections-35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-24, 25-29, 31-46, and 99-100 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "annealing the set of oligonucleotides" in independent claims 1, 39, and their dependent claims is unclear. It is not clear to which the set of oligonucleotides are annealed to: their parental strings or among themselves.

The term "low sequence similarity" in claim 9 is a relative term which renders the claim indefinite. The term is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 26-29 are dependent from claim 25, which has been canceled. Thus, the metes and bounds of claimed inventions of claims 26-29 are not clear.

Provisional Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-24, 26-29, 31-46, and 99-100 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 99-101, 105-112 of US copending Application No. 09/494,282.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759

F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-24, 26-29, 31-46, and 99-100 of the instant application are drawn to a method of making recombinant nucleic acids comprising steps of providing parental strings, aligning the strings and defining a set of character string subsequences, providing a set of oligonucleotides corresponding to the set of subsequences, annealing the oligonucleotides, and elongating one or more of the oligonucleotides.

Claims 99-101, 105-112 of US copending Application No. 09/494,282 are drawn to a method comprising providing parental strings, aligning the strings, applying a genetic operator such as crossover, selecting a set of character string subsequences, synthesizing a set of oligonucleotides corresponding to the set of subsequences for in vitro recombination.

The portions of the specification of copending Application No. 09/494,282 that supports the invention of claims 99-101, 105-112 include embodiment that would anticipate claims 1-24, 26-29, 31-46, and 99-100 of the instant application. The specification on page 4, lines 20-32 discloses that a set of oligonucleotides corresponding to parental strings are denatured and annealed to each and extended by a polymerase. Further, the set of genetic operators required in the instant claims are also disclosed in the specification of 09/494,282 on pages 13-15. Thus, claims 1-24, 26-29, 31-46, and 99-100 of the instant application cannot be considered patentably distinct over claims 99-101, 105-112 of US copending Application No. 09/494,282 when there are specifically recited embodiments that would anticipate the instant claims. Alternatively, claims 1-24, 26-29, 31-46, and 99-100 cannot be considered patentably distinct over 99-101, 105-112 of US copending Application No. 09/494,282 when there are specifically disclosed

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embodiments in the copending applications that support claims 99-101, 105-112 of the copending application and fall within the scope of claim 1-24, 26-29, 31-46, and 99-100 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claims 99-101, 105-112 of US copending Application No. 09/494,282 by selecting a specifically disclosed embodiment that supports those claims. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 99-101, 105-112.

Claim Objections

13. Claim 39 is objected to because the word "homolgous" appears to be misspelled.
14. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 comprises aligning parental strings for maximum identity, which indicates that the parental strings comprise at least one region of similarity. Thus, the limitation "at least one region of similarity" in claim 2 does not further limit claim 1.

Conclusion

15. No claim is allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael

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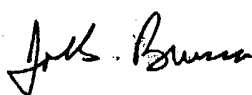
Woodward, Ph.D., can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst William Phillips whose telephone number is 571-272-0548, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shubo (Joe) Zhou, Ph.D.



Patent Examiner

 23 December 2001

JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER